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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/785,593	02/16/2001	Joseph D. Gresser	CSI-112AX	4390

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EXAMINER

PREBILIC, PAUL B

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 09/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

NK

Office Action Summary	Application No. 09/785,593	Applicant(s) GRESSER ET AL	
	Examiner Paul B. Prebilic	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-8,11-20,24-31 and 33 is/are pending in the application.
- 4a) Of the above claim(s) 5,7,8,13-15 and 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,6,11,12,16-20,25,26,28-30 and 33 is/are rejected.
- 7) ☒ Claim(s) 27 and 31 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

Election/Restrictions

Claims 5, 7, 8, 13-15, and 24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions or species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper Numbers 8 and 9.

Claims 16, 19, and 20 have been rejoined because the amendments thereto overcome the indefiniteness rejection that made them withdrawn.

Claim Objections

Claims 17 and 18 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 19 and 20, respectively. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 6, 11, 12, 16, 25 and 33 are rejected under 35 U.S.C. 102(e) as being anticipated by Agrawal (US 5,741,329). Agrawal reads on the claimed invention where

the preamble is not required for the interpretation of the claim body such that the claims are read thereon; see the abstract and columns 3 and 4. The scaffold for tissue in growth inherently has one or more voids as claimed. The void spaces are the pores of the device, and the polylactide-glycolide copolymer or polycaprolactone polymers are the polymers producing acidic products as claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3, 6, 11, 12, 16, 25, 30, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ray (US 4,961,740) in view of Agrawal (US 5,741,329). Ray discloses a interbody spinal fusion device as claimed where the device can be made of 100% resorbable material; see the abstract, Figure 1, column 1, lines 10-22 and column 4, lines 30-45. The interior cavity of Ray is the one or more voids as claimed. However, Ray fails to specify the resorbable material used and does not teach the use of buffering or neutralizing agents as claimed. However, Agrawal teaches that it was known to make the similar bone implants out of polylactic or polyglycolic acid polymers and to neutralize them with buffering agents such as hydroxylapatite (e.g. calcium hydroxylapatite); see the previously cited portions. Therefore, it would have been obvious to make the spinal implant of Ray out of the material of Agrawal for the same reasons that Agrawal uses the same in bone implants.

With regard to claim 3, the interior cavity is the one or more voids as claimed and it can be filled with bone growth induction substances; see the abstract of Ray.

With regard to claim 25, the polymers of Agrawal can be made from mixtures of resorbable polymers; see the abstract. Therefore, it would have been obvious to use a mixture of polymer in Ray for the same reasons as Agrawal and because Applicant has not stated that it is critical to use mixtures over other polymers.

With regard to claim 30, the substantially aligned polymer molecular chains as claimed are merely a description of a crystalline polymer. For this reason, it is the Examiner's position that it would have been obvious to use a crystalline polymer as the polymer of Ray as modified by Agrawal because the crystalline polymer would have greater strength as compared to amorphous polymers.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ray and Agrawal as applied to claims 1, 3, 6, 11, 12, 16, 25, 30, and 33 above, and further in view of Brantigan (US 5,192,327). Ray discloses packing the implant with bone chips, but fails to disclose the source thereof. However, Brantigan teaches that it was known to use patient's own bone into similar spinal implant in order to avoid using other bone graft material; see column 2, lines 44-51. Therefore, it is the Examiner's position that it would have been obvious to use the patient's own bone (i.e. autograft material) for the same reason that Brantigan teaches uses the same.

Claims 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ray and Agrawal as applied to claims 1, 3, 6, 11, 12, 16, 25, 30, and 33 above, and further in view of Dunn et al (US 4,655,777). Ray fails to disclose the use of

reinforcing fibers therewith. Dunn et al, however, teaches that it has been known to use reinforcing fibers in the resorbable polymer implant art; see the abstract. Hence, it is the Examiner's position that it would have been obvious to use reinforcing fibers in the resorbable polymer of Ray for the same reasons that Dunn et al uses the same.

Claims 26, 28, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ray and Agrawal as applied to claims 1, 3, 6, 11, 12, 25, 30, and 33 above, and further in view of Suggs (US 5,527,864). Ray fails to disclose the use of the particular resorbable materials as claimed. Suggs et al teaches that the claimed materials have been known and used in the art for some time; see the abstract and column 3, lines 27-40. Hence, it is the Examiner's position that it would have been obvious to replace or supplement the polymer of Ray with those of Suggs et al for the same reasons that Suggs et al uses the same.

Allowable Subject Matter

Claims 27 and 31 are rejected under double patenting doctrine only. If the double patenting rejection were overcome, these claims would be objected to as being dependent upon a rejected base claim or intervening claim. If written in independent form, they would be allowable over the prior art of record.

Response to Arguments

Applicant's arguments filed July 7, 2003 have been fully considered but they are not persuasive.

In response to the argument that Agrawal is not to a spinal fusion device (page 7 of the response), the Examiner asserts that the preamble is not required for a complete

interpretation of the claim body, which begins at "comprising." Furthermore, even if one gave weight to the preamble, the Examiner asserts that it is merely a statement of intended use and does not structurally limit the claim scope.

Applicants argue that Ray is drawn to a super-strength material yet Agrawal is not (page 8 of the response), the Examiner asserts that since Agrawal discloses bone and tooth replacements (see column 4, lines 53-64), Agrawal discloses super-strength implant materials to the extent that this language is limiting to Ray.

In response to the assertion that the Ray and Agrawal combination would not have a reasonable expectation of success (page 9 of the response), the Examiner disagrees and notes that Agrawal is presumed to disclose operable embodiments of bone and tooth replacement. For this reason, the Examiner asserts that there is a reasonable expectation of success for the combination.

In response to applicant's arguments against the references individually (Brantigan, Dunn, and Suggs), one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilio whose telephone number is (703) 308-2905. The examiner can normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for this Technology Center is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.


Paul Prebilio
Primary Examiner
Art Unit 3738

US 097855930HP1



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